UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST SAINT LOUIS DIVISION

		X
IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	:	**3:09-MD-02100-DRH-PMF** **MDL NO. 2100** **Judge David R. Herndon**
DANIELLE NICOLET and MICHAEL KUSSMAN, **Plaintiffs,**	:	**COMPLAINT AND JURY DEMAND**
vs.	:	**Civil Action No. 12-10861-DRH-PMF**
BAYER CORPORATION, **An Indiana corporation** **c/o Illinois Corporation Service C** **801 Adlai Stevenson Dr.** **Springfield, IL 62703,** **BAYER HEALTHCARE, LLC,** **A Delaware corporation** **c/o Illinois Corporation Service C** **801 Adlai Stevenson Dr.** **Springfield, IL 62703,** **BAYER PHARMACEUTICALS CORPORATION,** **A Delaware corporation** **400 Morgan Lane** **West Haven, CT 06516,** **BAYER HEALTHCARE PHARMACEUTICALS, INC.** **SOP Department** **Corporate Service Company** **Suite 400** **2711 Centerville Road** **Wilmington, DE 19805** **BAYER PHARMA AG,** **Eva Gardyan-Eisenlohr** **Head of Law & Patents** **Bayer Pharma AG**	:	

Müllerstrasse 178
D- 13353 Berlin
Germany

BAYER AG,
Leverkusen
North Rhine-Westphalia, Germany

BARR PHARMACEUTICALS, INC.
A Utah Corporation
c/o Corporation Service Company
2711 Centerville Road, Ste 400
Wilmington, DE 19808

BARR LABORATORIES, INC.
c/o Jennifer L. Fuller-Ricciardi
425 Privet Rd.
Horsham, PA 19044

TEVA PHARMACEUTICALS
INDURTIES, LTD
An Israeli Company
5 Basel Street
Petach, Tikva 49131
Israel

TEVA PHARMACEUTICALS USA, INC.
c/o Jennifer L. Fuller-Ricciardi
425 Privet Rd.
Horsham, PA 19044

Defendants.

COMPLAINT

Plaintiffs by their attorneys, Garrett Law Office, P.C., and for their Complaint against Defendants, alleges as follows:

I. THE PARTIES

1. This is an action brought by Plaintiff, DANIELLE NICOLET, who used the combination oral contraceptive Yaz, Yasmin and/or Ocella, also generically as

drospirenone and ethinyl estradiol (hereinafter collectively referred to as ("Yaz/Yasmin/Ocella").

2. Plaintiff, DANIELLE NICOLET, was prescribed and purchased and ingested Yaz/Yasmin/Ocella, and while using Yaz/Yasmin/Ocella suffered injuries to her gallbladder resulting in surgical removal on or about AUGUST 30, 2006. Plaintiff did not become aware that her use of Yaz/Yasmin/Ocella could have been the cause of her gallbladder disease and ultimate removal until JULY 2010.

3. Plaintiff, DANIELLE NICOLET, is a resident of HERMOSA BEACH, CALIFORNIA located in LAS ANGELES County.

4. Plaintiff, MICHAEL KUSSMAN, is the husband of Plaintiff, DANIELLE NICOLET, and is also a resident and citizen of HERMOSA BEACH, CALIFORNIA, located in LAS ANGELES County. Plaintiff, DANIELLE NICOLET, and her husband Plaintiff, MICHAEL KUSSMAN, were married at the time of her injuries.

5. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.000), exclusive of interest and costs.

6. Defendant, BAYER CORPORATION, is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205. Defendant, BAYER CORPORATION, is the sole member of Bayer Healthcare LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC.

7. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 400 Morgan Lane, West Haven, Connecticut.

8. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

9. At relevant times, Defendant, BAYER CORPORATION, was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin/Ocella. At relevant times, Defendant BAYER CORPORATION, conducted and sustained regular business in Illinois and engaged in substantial commerce and business activity in Illinois.

10. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. is the U.S. based pharmaceuticals unit of Schering Berlin, Inc. and is a division of Bayer Ag.

11. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is a corporate successor to Berlex Laboratories, Inc. (Berlex), which was formerly known as Berlex, Inc., and as such is obligated for its predecessor's liabilities.

Berlex was formally engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling directly and indirectly through third parties or related entities, the drug Yaz/Yasmin/Ocella.

12. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin/Ocella. At relevant times, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. conducted and sustained regular business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois.

13. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is the holder of the approved New Drug Application ("NDA") for Yaz/Yasmin/Ocella.

14. Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC., is the holder of the approved New Drug Application ("NDA") for Yasmin.

15. Berlex Laboratories International, Inc. was engaged in the business of researching, developing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin/Ocella. At all relevant times, Berlex Laboratories International, Inc. conducted and sustained regular business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and

business activity in Illinois. Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. As such, Defendant, BAYER HEALTHCARE PHARMACEUTICALS, INC. is liable for the actions and omissions of Berlex Laboratories International, Inc.

16. Defendant, BAYER HEALTHCARE, LLC, is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York, 10591. BAYER HEALTHCARE, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant, BAYER HEALTHCARE, LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin/Ocella. At relevant times, Defendant, BAYER HEALTHCARE, LLC, conducted and sustained regular business in Illinois by selling and distributing its products in Illinois and engaged in substantial commerce and business activity in Illinois.

17. Defendant, BAYER PHARMA AG, formerly known as Schering AG and Bayer Schering Pharma AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

18. Defendant, BAYER PHARMA AG, is a corporate successor of Schering AG and Bayer Schering Pharma AG.

19. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006. Bayer Schering Pharma AG was renamed Bayer Pharma AG effective July 1, 2011.

20. Defendant, BAYER PHARMA AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

21. Defendant, BAYER PHARMA AG, is the current owner of the patent(s) relating to the oral contraceptive Yasmin.

22. Defendant, BAYER PHARMA AG, is the current owner of the patent(s) relating to the oral contraceptive Yaz/Yasmin/Ocella.

23. Defendant, BAYER AG, is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

24. Defendant, BAYER AG is the third largest pharmaceutical company in the world.

25. Defendant, BAYER AG is the parent/holding company of all other names Defendants.

26. Defendant, BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

27. Defendants, BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER HEALTHCARE, LLC, BAYER PHARMA AG, and BAYER AG, are collectively referred to herein as "Bayer", "Bayer Defendants", or "Defendants."

28. Defendant BARR PHARMACEUTICALS, INC. is, and at all times relevant was, a corporation organized under the laws of the state of Utah having regularly established places of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677; 109 Morgan Lane, Plainsboro, New Jersey 08536; and 265 Livingston Street, Northvale, New Jersey 07647.

29. Defendant BARR LABORATORIES, INC. is, and at all relevant times, a corporation organized under the laws of the state of Delaware having regular and established places of business at One Belmont Avenue, Bala Cynwyd, Pennsylvania and 255 Summit Avenue, Montvale, New Jersey.

30. Defendant BARR LABORATORIES, INC. was a wholly owned subsidiary of Barr Pharmaceuticals, Inc.

31. Defendants BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC. shall be referred to herein as “Barr”, “Barr Defendants”, or “Defendants.”

32. Defendant TEVA PHARMACEUTICALS INDUSTRIES, LTD is, and at all times relevant was a pharmaceutical corporation organized under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

33. Defendant TEVA PHARMACEUTICALS USA is, and all times relevant was a pharmaceutical company organized under the laws of Delaware with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania.

34. Defendant TEVA PHARMACEUTICALS USA is an indirect wholly-owned subsidiary of TEVA PHARMACEUTICALS INDUSTRIES, LTD.

35. Defendants TEVA PHARMACEUTICALS INDUSTRIES, LTD and TEVA PHARMACEUTICALS USA, shall be referred to herein as "Teva", "Teva Defendants", or "Defendants."

II. JURISDICTION AND VENUE

36. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

37. Venue is proper under 28 U.S.C. §1391 in that substantial events giving rise to the claims asserted herein occurred within the Federal District of the Southern District of Illinois. Furthermore, Plaintiffs file this Complaint in this district pursuant to Case Management Order No. 9 entered by the honorable Judge R. Herndon in MDL No. 2100.

III. FACTUAL ALLEGATIONS

A. Nature of the Case

38. Plaintiffs brings this case against Defendants for damages associated with Plaintiff, DANIELLE NICOLET's, ingestion of the pharmaceutical drug Yaz/Yasmin/Ocella (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, as a direct result of her use of Yaz/Yasmin/Ocella, Plaintiff, DANIELLE NICOLET suffered injuries to her gallbladder resulting in surgical removal on or around AUGUST 30, 2006. Plaintiff did not become aware that her use of Yaz/Yasmin/Ocella could have been the cause of her gallbladder disease and ultimate removal until JULY 2010.

B. Bayer's Combined Oral Contraceptives – Yasmin and Yaz

39. Yazand Yasmin are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning that they contain both and estrogen component and a progestin component. Together, these hormonal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

40. Yaz and Yasmin were approved by the Food and Drug Administration for marketing in 2006 and 2001, respectively.

C. Yaz and Yasmin contain a "Fourth Generation" Progestin

41. The estrogen component in Yaz and Yasmin is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

42. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

43. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

44. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen (ethinyl estradiol), helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

45. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

46. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, which has been used in the lower dose birth control pills for decades.

47. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin marketed under the trade name, Ocella.

48. On June 24, 2008, Barr Laboratories, Inc. ("Barr"), which is now a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva"), announced that it had entered into a supply and licensing agreement with Bayer Defendants for the distribution of Ocella, which is the generic version of Yasmin. According to

Bayer's *Press Release*, under the terms of that agreement, Bayer supplies Ocella to Barr and Barr distributes Ocella in the U.S. under the Barr Laboratories label.

49. According to IMS sales data, Ocella had annual sales of approximately $170.2 million in the United States for the twelve months ending December 31, 2008.

50. Since drospirenone is new, there is insufficient data available to support its safe use, particularly compared with second generation progestins. In fact studies performed prior to FDA approval indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

51. As a diuretic, drospirenone can cause an increase in potassium levels in the blood. This can lead to a condition known as hyperkalemia (elevated blood potassium level). Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

52. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the legs where it can cause deep vein thrombosis, or can travel to the brain causing stroke.

53. In addition, drospirenone can cause gallbladder disease and kidney stone formation which have been reported with the use of drospirenone in Yaz, Yasmin and Ocella. As a result, surgical intervention is often required.

54. Indeed, during the brief time that Yaz, Yasmin and Ocella have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

55. In April 2002, **THE BRITISH MEDICAL JOURNAL** reported that the **DUTCH COLLEGE OF GENERAL PRACTITIONERS** recommended that older second generation birth control pills should be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

56. In February 2003, a paper entitled ***Thromboembolism Associated With the New Contraceptive Yasmin*** was published in **THE BRITISH MEDICAL JOURNAL,** detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

57. The FDA's adverse event data indicates staggering, serious adverse events that have been associated with Yaz, Yasmin and Ocella, including, but not limited to heart arrhythmias, electrolyte imbalance, hyponatremia, hyperkalemia, Hyperkalemia arrhythmias, atrial fibrillation, tachycardia bradycardia, myocardial infarction, strokes, transient ischemic attacks, blood clot formation, gallbladder and kidney disease and/or sudden death.

58. In fact, from the first quarter of 2004 through the third quarter of 2008, the FDA received reports for more than 50 deaths where the decedents were users of Yaz/Yasmin/Ocella. Because of under reporting, the actual number of people who suffered side effects associated with these medications is actually 10 to 100 times more than reported.

59. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

60. Some of those deaths reported occurred in women as young as 17 years old.

61. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yaz, Yasmin or Ocella.

62. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yaz/Yasmin/Ocella over other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded that "oral contraceptives with . . . drospirenone were associated with a significantly higher risk of venous thrombosis than oral contraceptives with evonogesterel." Lidegard, et al., *Hormonal contraception and risk of venous thromboembolism: natural follow up study*, **THE BRITISH MEDICAL JOURNAL** 2009, 330:**B**2921.

63. The second study found that Yaz/Yasmin/Ocella users have twice the risk of clotting event than users of birth control pills that contain levonorgestral. Vandenbroucke, et al., *The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study.* **THE BRITISH MEDICAL JOURNAL** 2009, 339:**B**2921.

64. Despite the wealth of scientific evidence, Defendants have not only ignored the increased risk of the development of the aforementioned injuries associated with the used of Yaz, Yasmin and Ocella, but they have, through their marketing and advertising campaigns, urged women to use Yaz, Yasmin or Ocella instead of other birth control pills that present a safer alternative.

D. Over-Promotion of Yaz/Yasmin/Ocella

65. Defendants market Yaz/Yasmin/Ocella as effective for the treatment of premenstrual dysphoric disorder (hereinafter referred to as "PMDD"), premenstrual syndrome (hereinafter referred to as "PMS") and moderate acne, in addition to its FDA-approved use as an oral contraceptive.

66. Defendants market Yaz/Yasmin/Ocella as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

67. Defendants market Yaz/Yasmin/Ocella as lacking certain side-effects, such as weight gain, bloating, and water retention, common to many other oral contraceptives.

68. However, because Yaz/Yasmin/Ocella contains the fourth generation progestin drospirenone, which is a diuretic, these drugs present additional health risks not associated with other birth control pills.

69. For example, prior to its sale to Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

70. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral

contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

71. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

72. More recently, Defendants advertised that its product Yaz/Yasmin/Ocella was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

73. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

74. In one of Defendants' commercials cited by the FDA, the song "*We're Not Gonna Take It*" plays in the background, while a series of young, fashionably dressed women kick away or puncture floating signs with labels saying "irritability" and "feeling anxious." Meanwhile, a voice over promotes Yaz as a "*pill that goes beyond the rest, with benefits like the ability to maintain clear skin.*"

75. Another one of Defendants' commercials is set to the tune of "*Goodbye to You*" and shows a variety of women next to balloons marked "*headaches,*" "*acne*" and "*feeling anxious,*" which float away, presumably after taking Yaz.

76. In response to these ads, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the

marketing was misleading because it promoted Yaz/Yasmin/Ocella for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone … which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

77. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

78. Indeed, the FDA felt Defendants' over promotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

79. During 2008, when the ads in question were broadcast on television, Defendants' sales of Yaz in the United States increased to approximately $616 million, from about $262 million in 2007. For 2008, Defendants' sales of Yasmin totaled about $382 million, or about 11 percent of the United States market.

80. In February 2009, Bayer Corporation settled 27 claims with Attorney Generals across the country, including Pennsylvania Attorney General, Thomas W. Corbett, Jr., for misleading marketing and sales practices of Yaz and Yasmin. The litigation alleged that Defendant Bayer Corporation overemphasized the benefits and minimized the risks of Yaz and Yasmin.

81. Defendants did not provide adequate warnings to doctors, the health care community and the public about the risk of serious adverse events that are described in this complaint.

82. As a result of the manufacture, marketing, advertising, promotion, distribution, the sale of Yaz, Yasmin and Ocella without adequate warnings about the risks of serious injuries, Plaintiff has sustained severe and permanent personal injuries.

83. As a result of Defendants' claim regarding the effectiveness and safety of Yaz, Yasmin and Ocella, Plaintiff's medical provide prescribed her and she ingested Yaz/Yasmin/Ocella.

E. Plaintiff's Use and Resulting Injuries

84. After taking Yaz/Yasmin/Ocella, as prescribed by her physician, Plaintiff, DANIELLE NICOLET, suffered injuries to her gallbladder resulting in surgical removal on or around AUGUST 30, 2006. Plaintiff did not become aware that her use of Yaz/Yasmin/Ocella could have been the cause of her gallbladder disease and ultimate removal until JULY 2010.

85. As a direct and proximate result of using Yaz/Yasmin/Ocella, Plaintiff, DANIELLE NICOLET, suffered the injuries described above.

86. Prior to Plaintiff, DANIELLE NICOLET's use of Yaz/Yasmin/Ocella, Defendants knew or should have known that use of Yaz/Yasmin/Ocella created an increased risk to consumers of serious personal injury, including gallbladder removal, deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

87. Despite the fact that Defendants know or should have known of the serious health risks associated with the use of Yaz/Yasmin/Ocella, Defendants failed to warn Plaintiff, DANIELLE NICOLET, and/or her health care providers of said serious risks before she used the product.

88. Had Plaintiff, DANIELLE NICOLET, and/or her health care providers known the risks and dangers associated with Yaz/Yasmin/Ocella, she would not have used Yaz/Yasmin/Ocella and would not have suffered the injuries described above.

89. As a direct and proximate result of her use of Yaz/Yasmin/Ocella, Plaintiff, DANIELLE NICOLET, suffered physical injury, including but not limited to, conscious pain and suffering, as a result of her gallbladder removal.

90. As a direct and proximate result of her use of Yaz/Yasmin/Ocella, Plaintiff, DANIELLE NICOLET, has suffered and will continue to suffer pecuniary and other losses.

91. As a direct and proximate result of Plaintiff, DANIELLE NICOLET's use of Yasmin and resulting injuries, her husband, Plaintiff, MICHAEL KUSSMAN, has suffered damages and harm, including but not limited to, emotional distress and has incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort.

IV. CAUSES OF ACTION

COUNT I

FRAUDULENT CONCEALMENT

92. Plaintiffs incorporates by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

93. Prior to Plaintiff's use of Yaz/Yasmin/Ocella and during the period in which Plaintiff actually used Yaz/Yasmin/Ocella, Defendants fraudulently suppressed material information regarding the safety and efficacy of Yaz/Yasmin/Ocella,

including information regarding increased adverse events, pre and post marketing deaths, a high rate of severe adverse event reports compared to other birth control pills, deaths, cardiac arrhythmia, cardiac arrest, intra cardiac thrombus, pulmonary embolism, deep vein thrombosis and stroke. Furthermore, Defendants fraudulently concealed the safety information about the use of drospirenone, the only birth control pills using this ingredient. As described above, drospirenone has several well known serious side effects that are not seen in other forms of birth control. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Yaz/Yasmin/Ocella strong.

94. Defendants fraudulently concealed safety issues with Yaz/Yasmin/Ocella in order to induce physicians to prescribe and patients, including Plaintiff, to purchase and use Yaz/Yasmin/Ocella.

95. At the time Defendants concealed the fact that Yaz/Yasmin/Ocella was not safe, Defendants were under a duty to communicate this information to physicians, the FDA, the Healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Yaz/Yasmin/Ocella.

96. Plaintiff and Plaintiff's prescribing doctor relied upon the Defendants' outrageous untruths regarding the safety of Yaz/Yasmin/Ocella.

97. As a direct and proximate result of Defendants' malicious and/or intentional concealment of material life-altering information from Plaintiff and Plaintiff's prescribing doctor, Defendants caused or contributed to Plaintiffs' injuries.

98. It is unconscionable and outrageous that Defendants would risk the lives of consumers. Despite this knowledge, the Defendants made conscious decisions not

to redesign, label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct rises to the level necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

99. Defendants' fraudulent concealment tolled the statute of limitations because only Defendants knew the true dangers associated with the use of Yaz/Yasmin/Ocella as described herein. Defendants did not disclose this information to the Plaintiff, the prescribing doctor, the Healthcare community or the general public. Without full knowledge of the dangers of Yaz/Yasmin/Ocella, Plaintiff and Plaintiff's lawyer could not evaluate whether a person who was injured by Yaz/Yasmin/Ocella had a valid claim.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II

STRICT LIABILITY

100. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows.

101. At the time of Plaintiff's injury, Defendants' pharmaceutical, Yaz/Yasmin/Ocella, was defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

102. The Yaz/Yasmin/Ocella was in the same or substantially similar condition as it was when it left the possession of Defendants.

103. Plaintiff did not misuse or materially alter the Yaz/Yasmin/Ocella.

104. Defendants are strictly liable for Plaintiff's injuries in the following ways:

a. The pharmaceutical Yaz/Yasmin/Ocella as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition.

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell Yaz/Yasmin/Ocella.

c. Defendants failed to warn and/or place adequate warnings and instructions on Yaz/Yasmin/Ocella.

d. Defendants failed to adequately test Yaz/Yasmin/Ocella.

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of Yaz/Yasmin/Ocella.

f. A feasible alternative design existed that was capable of preventing Plaintiff's injury.

105. Defendants' actions and omissions were the direct and proximate cause of Plaintiffs' injuries.

106. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and

suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

107. Plaintiffs incorporate by reference all preceding paragraphs as if set forth fully at this point, and further alleges on information and belief as follows:

108. At the time Defendants marketed, distributed, and sold Yaz/Yasmin/Ocella to Plaintiff, Defendants warranted that Yaz/Yasmin/Ocella was merchantable and fit for the ordinary purposes of which it was intended.

109. Members of the consuming public, including consumers such as Plaintiff, were intended third-party beneficiaries of the warranty.

110. Yaz/Yasmin/Ocella was not merchantable and fit for its ordinary purpose, because it had a propensity to lead to the serious personal injuries described in this complaint.

111. Plaintiff reasonably relied on Defendants' representations that Yaz/Yasmin/Ocella was safe and free of defects and was a safe means of birth control.

112. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injuries.

113. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV

BREACH OF IMPLIED WARRANTY OF FITNESS

FOR A PARTICULAR PURPOSE

114. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

115. Defendants sold Yaz/Yasmin/Ocella with an implied warranty that it was fit for the particular purpose of safe birth control, which offered other benefits such as reduced bloating, reduced mood swings, improved complexion, and reduced the severity of women's menstruation.

116. Members of the consuming public, including consumers such as Plaintiff, were intended third-party beneficiaries of the warranty.

117. Yaz/Yasmin/Ocella was not fit for the particular purpose of a safe birth control pill without serious risk of personal injury, which risk is much higher that other birth control pills.

118. Plaintiff reasonably relied on Defendants' representations that Yaz/Yasmin/Ocella was safe and effective for use as a birth control method.

119. Defendants' breach of implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries.

120. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V

NEGLIGENT FAILURE TO WARN

121. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

122. Before Plaintiff used Yaz/Yasmin/Ocella, and during the period in which she used it, Defendants knew or had reason to know that Yaz/Yasmin/Ocella was dangerous and created an unreasonable risk of bodily harm to consumers.

123. Defendants had a duty to exercise reasonable care and to warn end users of the dangerous conditions or of the facts that made Yaz/Yasmin/Ocella likely to be dangerous.

124. Despite the fact that Defendants knew or had reason to know that Yaz/Yasmin/Ocella was dangerous, Defendants failed to exercise reasonable care in warning the medical community and consumers, including Plaintiff, of the dangerous conditions and facts that made Yaz/Yasmin/Ocella likely to be dangerous.

125. The Plaintiffs' injuries were a direct and proximate result of Defendants' failure to warn of the dangers of Yaz/Yasmin/Ocella.

126. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI

NEGLIGENCE

127. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

128. Defendants have a duty to exercise reasonable care in the manufacture, sale and distribution of Yaz/Yasmin/Ocella, including a duty to ensure that the product did not cause unreasonably dangerous side effects to users.

129. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, and distribution of Yaz/Yasmin/Ocella, in that the Defendants knew or should have known that the drug created a high risk of unreasonable harm.

130. Defendants were negligent in the design, manufacture, advertising, warning, marketing and sale of Yaz/Yasmin/Ocella, in that, among other things, they:

a. Failed to use due care in designing and manufacturing Yaz/Yasmin/Ocella, so as to avoid the aforementioned risks to individuals;

b. Failed to accompany the drug with proper warnings regarding all possible adverse side effects associated with its use, and the comparative severity and duration of such adverse effects. The warnings given did not reflect accurately the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of Yaz/Yasmin/Ocella;

d. Placed an unsafe product into the stream of commerce;

e. Were otherwise careless or negligent.

131. Despite the fact that Defendants knew or should have known that Yaz/Yasmin/Ocella caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market Yaz/Yasmin/Ocella to consumers, including the medical community and Plaintiff.

132. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII

NEGLIGENT MISREPRESENTATION

133. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

134. Prior to Plaintiff first using Yaz/Yasmin/Ocella and during the period in which she used Yaz/Yasmin/Ocella, Defendants misrepresented that Yaz/Yasmin/Ocella was a safe and effective means of birth control. Defendants also failed to disclose material facts regarding the safety and efficacy of Yaz/Yasmin/Ocella, including information regarding increased adverse events, harmful side effects, and results of a clinical study showing the use of the medication to be life-threatening.

135. Defendants had a duty to provide Plaintiff, physicians, and other consumers with true and accurate information and warnings of any known risks and side effects of the pharmaceuticals they marketed, distributed and sold.

136. Defendants knew or should have known, based on their prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures with Yaz/Yasmin/Ocella, that their representations regarding Yaz/Yasmin/Ocella were false, and that they had a duty to disclose the dangers of Yaz/Yasmin/Ocella.

137. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including Plaintiff, to act in reliance by purchasing Yaz/Yasmin/Ocella.

138. Plaintiff justifiably relied on Defendants' representations and non-disclosures by purchasing and using Yaz/Yasmin/Ocella.

139. Defendants' misrepresentations and omissions regarding the safety and efficacy of Yaz/Yasmin/Ocella was a direct and proximate cause of Plaintiffs' injuries.

140. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNTY VIII

BREACH OF EXPRESS WARRANTY

141. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

142. Defendants expressly warranted that Yaz/Yasmin/Ocella was safe and effective to members of the consuming public, including Plaintiff.

143. Members of the consuming public, including consumers such as Plaintiff, were intended third-party beneficiaries of the warranty.

144. Defendants marketed, promoted and sold Yaz/Yasmin/Ocella as a safe method of birth control.

145. Yaz/Yasmin/Ocella does not conform to these express representations because Yaz/Yasmin/Ocella is not safe and has serious side effects, including death.

146. Defendants breached their express warranty in one or more of the following ways:

a. Yaz/Yasmin/Ocella, as designed, manufactured, sold and/or supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on Yaz/Yasmin/Ocella;

c. Defendants failed to adequately test Yaz/Yasmin/Ocella;

d. Defendants failed to provide a timely and adequate post-marketing warnings and instructions after they knew the risk of injury from Yaz/Yasmin/Ocella.

147. Plaintiff reasonably relied upon Defendants' warranty that Yaz/Yasmin/Ocella was safe and effective when she purchased and used the medication.

148. Plaintiffs' injuries were the direct and proximate result of Defendants' breach of their express warranty.

149. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX

FRAUD

150. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

151. Defendants widely advertised and promoted Yaz/Yasmin/Ocella as a safe and effective medication.

152. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

153. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Yaz/Yasmin/Ocella as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with the use of the medication, including the risks described in this Complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

154. Had Plaintiff been aware of the hazards associated with Yaz/Yasmin/Ocella, Plaintiff would not have consumed the product that led proximately to Plaintiff's adverse health effects.

155. Defendants' advertisements regarding Yaz/Yasmin/Ocella made material misrepresentations to the effect that Yaz/Yasmin/Ocella was a safe and effective medication, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing customers, such as Plaintiff, to purchase such product. Plaintiff relied on these material misrepresentations when deciding to purchase and consume Yaz/Yasmin/Ocella.

156. Upon information and belief, Plaintiff avers fact, Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Yaz/Yasmin/Ocella with the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X

VIOLATION OF THE CALIFORNIA CONSUMER LEGAL REMEDIES ACT Cal. Civ. Code § 1750, et seq.

157. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth at this point, and further alleges on information and belief as follows:

158. Defendants knew, or in the exercise of reasonable care should have known, that Yaz/Yasmin was not reasonably safe as designed, manufactured, tested, marketed and distributed.

159. Defendants knew that Yaz/Yasmin carried the increased risk of serious adverse events, including thrombotic injuries such as blood clots, pulmonary emboli, strokes, and damage to the gallbladder.

160. Defendants knew that the heightened risk of serious adverse events, including thrombotic injuries such as blood clots, pulmonary emboli, strokes and damage to the gallbladder was important information to consumers, such as Plaintiff.

161. Defendants committed a deceptive act, in violation of the California Consumer Legal Remedies Act when they intentionally failed to disclose the heightened risk of the serious adverse event described above.

162. Defendants' failure to disclose the heightened risk of the serious adverse events described above was likely to cause substantial injury to consumers, and did cause substantial injury to Plaintiff

163. By reason of the forgoing, Plaintiff was and will be caused bodily injury, pain,

suffering, and economic loss.

164. Defendants' failure to disclose the heightened risk of the serious adverse events described above was willful and knowing, entitling Plaintiff to all damages available under the California Consumer Legal Remedies Act.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial in accordance with Case Management Order #9 issued by United States District Court Judge David R. Herndon;
2. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs provided by law;
3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the

Plaintiffs in a amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding all applicable statutory damages of the state whose law will govern this action;
5. Awarding Plaintiffs reasonable attorneys' fees;
6. Awarding Plaintiffs the costs of these proceedings; and
7. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

DATED: May 9, 2012

Respectfully submitted,

/s/Jackqualyn R. Quinton

TONY EDWARDS
MARK S. THETFORD
JACKQUALYN R. QUINTON
The Edwards Law Firm
8282 S. Memorial Rd., Ste. 100
Tulsa, OK 74133
Telephone: (800) 304-9246
Facsimile: (918) 615-3558
tedwards@edwardslawok.com
mthetford@edwardslawok.com
jquinton@edwardslawok.com
Attorney for Plaintiff